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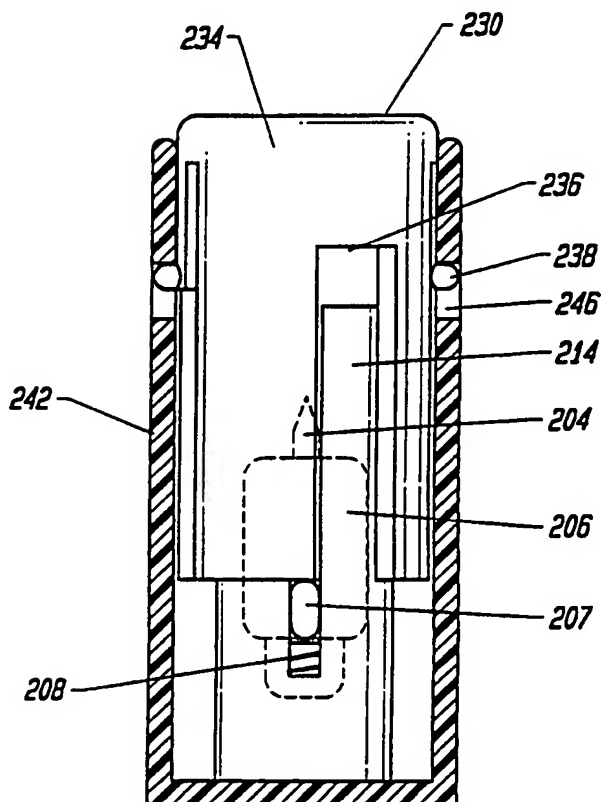


## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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**(54) Title:** LANCET DEVICE**(57) Abstract**

A lancet device includes a body (242) within which is slidably located a trigger (224) and fixedly located a base. The base (214) contains, in an armed position, the lance (202) with its needle (204) and a spring affixed to the lance. The trigger includes means to release the lance during use. In preferred embodiment, the lancet device of the present invention is self-activated by the finger (or other body part) to be pierced. Depression of the trigger with the finger releases the lance and the spring so that the needle protrudes through an orifice in the end of trigger and pierces the tissues. Because the spring is held in a pre-armed position, release of the spring is consistent, and reproducibility of incision is well controlled.



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**LANCET DEVICE****BACKGROUND OF THE INVENTION**

This invention relates to a lancet device for use in taking capillary blood samples by pricking a body tissue, such as a fingertip.

5           In the case of certain diseases, such as diabetes, or test kits, such as cholesterol test kits, a patient is required to provide small specimens of blood for analysis. This involves pricking a finger or other suitable body part in  
10           order to obtain the blood specimen. It is physiologically and psychologically difficult for many people to prick their own finger with a hand-held needle, which must be sterile.

15           Other lancet devices for obtaining blood samples, such as are disclosed in U.S. Patent Nos.

4,869,249 and 4,817,603, include a cap which is used to protect the needle or to keep the needle sterile. This makes manufacturing of these devices more difficult and costly, and makes the device harder to use.

In other devices, a spring used to shoot a needle into the tissue is compressed during use by the trigger mechanism, which can lead to misfiring or skewing of the spring so that the incision made is not suitable for obtaining a blood sample. Also, two hands are required for operation of many of these devices.

Thus, there is a need for a simple, inexpensive, reliable, self-activating, disposable lancet device in which reproducibility of suitable incisions is well controlled.

#### SUMMARY OF THE INVENTION

It is an object of the present invention to provide an improved lancet device.

In one embodiment, the present invention provides a lancet device comprising a body within which is slidably located a trigger and fixedly located a base. The base contains, in an armed position, a lance with its needle and a spring affixed to the lance. The trigger includes means to release the lance during use.

In a preferred embodiment, the lancet device of the present invention is self-activated by the finger (or other body part) to be pierced. Depression of the trigger with the finger releases the lance and the spring so that the needle protrudes through an orifice in one end of the trigger and pierces the tissue of the finger. Because the spring is held in a pre-armed

position, release of the spring is consistent, and reproducibility of incision is well controlled.

Other objects, features and advantages of the present invention will become apparent from the following detailed description when taken in conjunction with the accompanying drawings.

#### BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings, which are incorporated in and form a part of this specification, illustrate embodiments of the invention and, together with the description, serve to explain the principles of the invention:

FIG. 1 shows one embodiment in a longitudinal cross-section through the assembled lancet device.

FIG. 2 is a side view of the lance of the embodiment shown in FIG. 1.

FIG. 3 is a side view of the spring of the embodiment shown in FIG. 1.

FIG. 4 is a side view of the base of the embodiment shown in FIG. 1.

FIG. 5 is a side view of the trigger of the embodiment shown in FIG. 1.

FIG. 6 is a side view of the body of the embodiment shown in FIG. 1.

FIG. 7 shows the lancet device of the embodiment shown in FIG. 1 in firing position.

FIG. 8 shows the lancet device of the embodiment shown in FIG. 1 in the retracted position after it has been fired.

5 FIG. 9 shows a side view of another embodiment of the assembled lancet device.

FIG. 10 is a side view of the lance of the embodiment shown in FIG. 9.

10

FIG. 11 is a side view of the spring of the embodiment shown in FIG. 9.

15 FIGS. 12a and 12b are side views of the body of the embodiment shown in FIG. 9.

FIG. 13 is a side view of the trigger of the embodiment shown in FIG. 9.

20 FIG. 14 is a longitudinal cross-section through the assembled lancet device of the embodiment shown in FIG. 9.

25 FIG. 15 shows the lancet device of the embodiment shown in FIG. 9 in firing position.

FIG. 16 shows the lancet device of the embodiment shown in FIG. 9 in the retracted position after it has been fired.

30

FIGS. 17a and 17b show side views of the alternate lance for each embodiment.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Reference will now be made in detail to the preferred embodiments of the invention, examples of which are illustrated in the accompanying drawings. While the invention will be described in conjunction with the preferred embodiments, it will be understood that they are not intended to limit the invention to those embodiments. On the contrary, the invention is intended to cover alternatives, modifications and equivalents, which may be included within the spirit and scope of the invention as defined by the appended claims.

One embodiment of the disposable lancet device 100 shown assembled in FIG. 1 and in an exploded view in FIGS. 2-6 comprises a body 42 with a lip 46 extending from an aligning ring 52. The trigger 24 is slidably located in barrel 54 of body 42. Its end 30 containing an orifice 32 is aligned so that end 30 is in about the same plane 48 as the edge of lip 46 which is at the open end of body 42.

In a preferred embodiment, end 30 of trigger 24 is aligned in plane 48 by means of aligning edge 38 on trigger 24 and aligning ring 52 on inner surface 44 of body 42.

Means are provided for guiding and centering trigger 24 in barrel 54 of body 42. In a preferred embodiment, guiding ring 40 of trigger 24 serves this function.

The base 14 is fixedly attached to body 42. In a preferred embodiment, this is provided by means of snap fit edge 22 which is in contact with snap fit edge 50 of base 42. Other means of attachment, such as sonic welding, are also possible.



End 12 of spring 8 is fixedly attached to button 13 of base 14. End 10 of spring 8 is fixedly attached to shaft 6 of lance 2. Spring 8, shaft 6 and needle 4 thus provide a lance means.

5 In a preferred embodiment, end 12 is greater in diameter than end 10 to form a tapered spring configuration. Using this tapered spring configuration allows the coils of spring 8 to compress within one another without twisting when

10 they are compressed in an armed position. When a uniform diameter spring is compressed, it may twist or skew. Thus, using a tapered spring helps ensure reproducible release without skewing of the spring. This provides reproducible, centered,

15 piercing force to the lance. In one preferred embodiment, end 12 is about 250 mils in diameter and end 10 is about 150 mils in diameter.

Base 14 comprises retaining means to keep lance 2 and spring 8 in a pre-armed position

20 in well 16. In a preferred embodiment, shaft 6 of lance 2 has an edge 7 which will be caught by clip 20 of arm 18 of base 14 when the lancet device 100 is in the armed position. Spring 8 is compressed, edge 7 is caught by clips 20 of base 14 so that

25 base 14 retains lance 2 and spring 8 in an armed position in well 16. The lance means is thus located in base 14 during manufacture, shipping and storage of the device prior to use.

To use lancet device 100, a body part,

30 such as a finger, to be pierced is placed over orifice 32 and trigger 24 is then depressed. This causes clip-deflecting edges 36 to spread arms 18 and release lance 2 and spring 8. Needle 4 is centered and guided through the hollow center 26

35 of trigger 24 by shaft 6. The force of

decompression of spring 8 pushes needle 4 through orifice 32 to pierce the finger depressing trigger 24. This can be seen in FIG. 7. The depth of penetration of needle 4 is controlled by the  
5 length of the needle and the thickness of end wall 34. Because the body part to be pierced is the body part which depresses trigger 24, this lancet device is self-activating. This feature makes the lancet device of the present invention simple to  
10 use, as it may be operated with one hand. In one preferred embodiment, end wall 34 is 20 to 60 mils thick and the protruding end of needle 4 is 1 to 2.5 mm long.

In another embodiment the disposable  
15 lancet device 200 shown assembled in FIGS. 9 and 14 and in an exploded view in FIGS. 10-13 comprises a body 242. The trigger 224 is slidably located in barrel 254 of body 242. Its end 230 containing an orifice 232 is aligned so that end  
20 230 is in about the same plane 248 as the open end of body 242.

In a preferred embodiment, end 230 of trigger 224 is aligned in plane 248 by means of pins 238 of trigger 224 and slots 246 of body 242.

25 Means are provided for guiding and centering trigger 224 in barrel 254 of body 242. In a preferred embodiment, pins 238 of trigger 224 and slots 246 of body 242 serve this function as well.

30 The base 214 is inside barrel 254 of body 242. In a preferred embodiment, base 214 is a portion of the same molded piece as body 242.

Spring 208 is fixedly attached to base 214 at end 212. Spring 208 is fixedly attached to  
35 shaft 206 of lance 202 at end 210. Spring 208,

shaft 206 and needle 204 thus provide a lance means. In a preferred embodiment, end 212 is greater in diameter than end 210 to form a tapered spring configuration. As described in the  
5 previous embodiment, using this tapered spring configuration allows the coils of spring 208 to compress within one another without twisting when they are compressed in an armed position. This provides reproducible, centered, piercing force to  
10 the lance. In one preferred embodiment, end 212 is about 250 mils in diameter and end 210 is about 150 mils in diameter.

Base 214 comprises well 216 wherein lance 202 and spring 208 are loaded and retained.  
15 In a preferred embodiment, shaft 206 of lance 202 has arms 207 which line up with slots 220 in base 214. When trigger 224 is inserted into barrel 254 of base 242, it pushes against arms 207 of lance 202, sliding the lance into well 216 of base 214.  
20 This compresses spring 208. When pins 238 of trigger 224 engage slots 246 of body 242, they snap in place, retaining lance 202 and spring 208 in a compressed, armed position in well 216. The lance means is thus located pre-armed in base 214  
25 during manufacture, shipping and storage of the device prior to use.

To use lancet device 200, a body part, such as a finger, to be pierced is placed over orifice 232 and trigger 224 is then depressed.  
30 Pins 238 sliding in angled slots 246 cause trigger 224 to rotate. When trigger 224 is fully depressed slots 236 are aligned with slots 220 of base 214. This releases lance 202 and spring 208. Slots 246 can be at angles from 10° to 80°. In a

preferred embodiment, the angle of slots 246 can be from 30° to 60°.

Lance 202 is centered and guided by shaft 206 and arms 207 within base 214. The force of decompression of spring 208 pushes needle 204 through orifice 232 to pierce the finger depressing trigger 224. This can be seen in FIG. 15. The depth of penetration of needle 204 is controlled by the length of the needle and the thickness of end wall 234. Because the body part to be pierced is the body part which depresses trigger 224, this lancet device is self-activating. This feature makes the lancet device of the present invention simple to use, as it may be operated with one hand. In one preferred embodiment, end wall 234 is 20 to 60 mils thick and the protruding portion of needle 204 is 1 to 2.5 mm long.

In either embodiment, when the spring completes its over-extension after release and returns to its regular, un-armed length, the needle is completely within the trigger, so there is little or no danger of accidental needle exposure from the device after use. This can be seen in FIGS. 8 and 16.

The shaft of the lance is greater in diameter than the orifice in the trigger to prevent over-extension of the needle. The orifice is greater in diameter than the needle to allow easy withdrawal of the needle back into the hollow center of the trigger.

In either embodiment, more than one needle may be included in the lance. This alternate configuration may provide a more suitable incision for some uses. In preferred

embodiments, as seen in FIGS. 17a and 17b, two needles are used.

Various dimensions, shapes and structures can be used for the various components of the lancet device of the present invention.

The body, trigger, shaft, edge, and base may be circular, oval, square, rectangular or other appropriate shape in cross-section.

Conveniently, the base, trigger and body are injection molded using an appropriate plastics material. In a preferred embodiment, they are made of polystyrene.

The lancet device of the present invention may be utilized for human or veterinary use.

The foregoing descriptions of specific embodiments of the present invention have been presented for purposes of illustration and description. They are not intended to be exhaustive or to limit the invention to the precise forms disclosed, and it should be understood that many modifications and variations are possible in light of the above teaching. The embodiments were chosen and described in order to best explain the principles of the invention and its practical application, to thereby enable others skilled in the art to best utilize the invention and various embodiments with various modifications as are suited to the particular use contemplated. It is intended that the scope of the invention be defined by the Claims appended hereto and their equivalents.

WHAT IS CLAIMED IS:

1.           A lancet device, comprising  
            a lance, including a needle and a shaft;  
            a spring, one end of which is fixedly  
attached to said shaft of said lance;  
5           means for retaining said lance and  
spring in a compressed armed position prior to  
use;  
            a trigger, including a barrel to  
slidably accept said lance, an end with an orifice  
10          to allow said needle to protrude through said  
orifice when said lance and spring are released  
from said armed position to pierce human or other  
animal tissue, and means for releasing said lance  
and spring from said armed position during use;  
15          a body, including a barrel to slidably  
accept said trigger, a base with a well wherein  
said lance and spring are located, and an open end  
distal from said base, said open end being in  
about the same plane as the face of said orifice-  
20          containing end of said trigger when said trigger  
is inserted into said body;  
            means for fixedly attaching said base to  
said body; and  
            means for fixedly attaching said spring  
25          to said base.
2.           A lancet device comprising  
            lance means including a needle, a shaft  
and a spring, wherein one end of said spring is  
attached to said shaft,  
5           a base portion including a well wherein  
said lance means is normally located, said base

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portion including means for retaining said lance  
means in a compressed, armed position,

10 means for fixedly attaching the other  
end of said spring to said base,  
a trigger portion including a first  
shape having an outer surface and a hollow center  
to slidably accept said lance means, said trigger  
portion including one end with an orifice,

15 a body portion including a second shape  
having an inner surface, a hollow center, and  
apertures in both ends to slidably accept said  
trigger portion and said base portion,

said lancet device further including  
20 means for releasing said lance means including  
said needle from said armed position through at  
least said trigger portion including said orifice  
when sufficient pressure is applied from one end  
of said trigger portion to said base portion.

3. A lancet device as in Claim 2 including  
means for retracting said lance means including  
said needle back within said body portion after  
said lance means has been released through said  
5 trigger portion.

4. A lancet device, comprising  
a lance, including a needle and a shaft;  
a spring, one end of which is fixedly  
attached to said shaft of said lance;  
5 a base, including a well wherein said  
lance and spring are located, and means for  
retaining said lance and spring in a compressed  
armed position prior to use;

means for fixedly attaching the other  
10 end of said spring to said base;

a trigger, including a barrel with an outer surface and a hollow center to slidably accept said lance, an end with an orifice to allow said needle to protrude through said orifice when  
5 said lance and spring are released from said armed position to pierce human or other animal tissue, and means for releasing said lance and spring from said armed position during use;

means for controlling the depth of  
10 penetration of said needle into said tissue;

a body, including a barrel with an inner surface, a hollow center, and apertures in both ends to slidably accept said trigger and fixedly accept said base;

15 means for fixedly attaching said base to said body;

means for aligning said orifice-containing end of said trigger in a plane with the end of said body distal from said base; and

25 means for centering and guiding said trigger in said body.

5. A device as in Claim 4, wherein said spring comprises a tapered spring with a greater diameter at said end attached to said base.

6. A device as in Claim 4 wherein said retaining means comprises arms with clips to hold said shaft of said lance.

7. A device as in Claim 4 wherein said means for controlling the depth of penetration comprises having a specific wall thickness of said orifice-containing end of said trigger and a  
5 specific length of said needle.



8. A device as in Claim 4 wherein said means of releasing said lancet and spring comprises depressing said trigger.

9. A device as in Claim 8 wherein said trigger is depressed by a human or animal body part to be pierced by said needle.

10. A device as in Claim 4 wherein said body includes a lip extending out from the end of said body, a distal end of said lip being in about the same plane as the face of said orifice-containing  
5 end of said trigger when said trigger is inserted in said body.

11. A device as in Claim 4 wherein said lance includes a plurality of needles.

12. A device as in Claim 4 wherein said means for centering and guiding said trigger comprises one or more rings on said outer surface of said trigger.

13. A device as in Claim 4 wherein said means for aligning said trigger comprises a ring on said outer surface of said trigger which abuts with a ring on said inner surface of said body.

14. A device as in Claim 4 wherein said base, trigger and body are made of polystyrene.

15. A device as in Claim 4 wherein said base, trigger and body are injection molded.

16. A lancet device, comprising:

a lance, including a needle of a specific length and a shaft with an edge;

5 a tapered spring, the narrow diameter end of which is fixedly attached to said shaft of said lance;

10 a base, including a well wherein said lance and spring are located, and a plurality of arms with clips to hold said edge of said shaft of said lance for retaining said lance and spring in a compressed armed position prior to use;

means for fixedly attaching the large diameter end of said spring to said base;

15 a trigger, including a barrel with an outer surface and a hollow center to slidably accept said lance, an end with an orifice to allow said needle to protrude through said orifice when said lance and spring are released from said armed position to pierce human or other animal tissue, said end having a specific wall thickness for  
20 controlling the depth of penetration of said needle of specific length into said tissue, and clip-deflecting edges to spread said arms and release said lance and spring from said armed position when said trigger is depressed by a body  
25 part to be pierced;

30 a body, including a barrel with an inner surface, a hollow center, and apertures in both ends to slidably accept said trigger and fixedly accept said base, and a lip extending out from a first end of said body, a distal end of said lip being in about the same plane as the face of said orifice-containing end of said trigger when said trigger is inserted into said body;

35 means for fixedly attaching said base to  
said body;

a ring on said outer surface of said  
trigger in abutment with a ring on said inner  
surface of said body for aligning said orifice-  
40 containing end of said trigger in a plane with  
said lip; and

one or more rings on said outer surface  
of said trigger for centering and guiding said  
trigger in said body.

17. A lancet device, comprising

a lance, including a needle and a shaft;

a spring, one end of which is fixedly  
attached to said shaft of said lance;

5 a base, including a well wherein said  
lance and spring are located;

means for fixedly attaching the other  
end of said spring to said base;

a trigger, including a barrel to  
10 slidably accept said lance, means for retaining  
said lance and spring in a compressed armed  
position prior to use, an end with an orifice to  
allow said needle to protrude through said orifice  
when said lance and spring are released from said  
15 armed position to pierce human or other animal  
tissue, and rotational means for releasing said  
lance and spring from said armed position during  
use;

means for controlling the depth of  
20 penetration of said needle into said tissue;

a body, including a barrel to slidably  
accept said trigger and fixedly accept said base,  
an open end distal from said base, said open end  
being in about the same plane as the face of said

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orifice-containing end of said trigger when said trigger is inserted into said body, and means for retaining said trigger in said barrel;

25                    means for fixedly attaching said base to said body;

                  means for aligning said orifice-containing end of said trigger in a plane with said lip; and

30                    means for centering and guiding said trigger rotatably in said body.

18.            A device as in Claim 17, wherein said lance includes a plurality of needles.

19.            A device as in Claim 17 wherein said rotational retaining means comprises one or more pins on said trigger which engage one or more slots in said body.

20.            A device as in Claim 17 wherein said means for controlling the depth of penetration comprises having a specific wall thickness of said orifice-containing end of said trigger and a  
5                    specific length of said needle.

21.            A device as in Claim 17 wherein said rotational means of releasing said lancet and spring comprises depressing said trigger.

22.            A device as in Claim 21 wherein said trigger is depressed by a human or animal body part to be pierced by said needle.

23. A device as in Claim 17 wherein said means for attaching said base comprises molding said base and said body as a single piece.

24. A device as in Claim 17 wherein said means for centering and guiding said trigger comprises one or more pins on said trigger engaged with one or more slots of said body.

25. A device as in Claim 17 wherein said means for aligning said trigger comprises one or more pins on said trigger engaged with one or more slots of said body.

26. A device as in Claim 17 wherein said base, trigger and body are made of polystyrene.

27. A device as in Claim 17 wherein said base, trigger and body are injection molded.

28. A device as in Claim 19 wherein said slots are at an angle between 10° and 80°.

29. A lancet device, comprising:  
a lance, including a needle of a specific length and a shaft with one or more arms;  
a spring, one end of which is fixedly  
5 attached to said shaft of said lance;  
a trigger, including a barrel with an outer surface, one or more slots and a hollow center to slidably accept said lance, an end having a specific wall thickness and an orifice,  
10 an end distal from said orifice-containing end to engage said arms of said lance to compress said

spring, and one or more pins on said outer surface;

15           a body, including a barrel, a hollow center to slidably accept said trigger, a base with a well wherein said lance and spring are located in a compressed armed position prior to use, one or more angled slots in said barrel for engaging said pins of said trigger, and an end  
20   distal from said base being in about the same plane as the face of said orifice-containing end of said trigger when said pins of said trigger are engaged in said slots of said body;

          means for fixedly attaching the other  
25   end of said spring to said base;

          one or more slots in said base to slidably accept said arms of said lance;

          said distal end of said trigger retaining said lance and spring in said compressed  
30   armed position in said well when said pins in said trigger are engaged in the top of said angled slots of said body; and

          said angled slots of said body guiding said pins of said trigger to rotate said trigger  
35   when said trigger is depressed so that said slots of said trigger align with said slots of said base and said arms of said lance to release said lance and spring to allow said needle to protrude through said orifice to pierce human or other  
40   animal tissue.

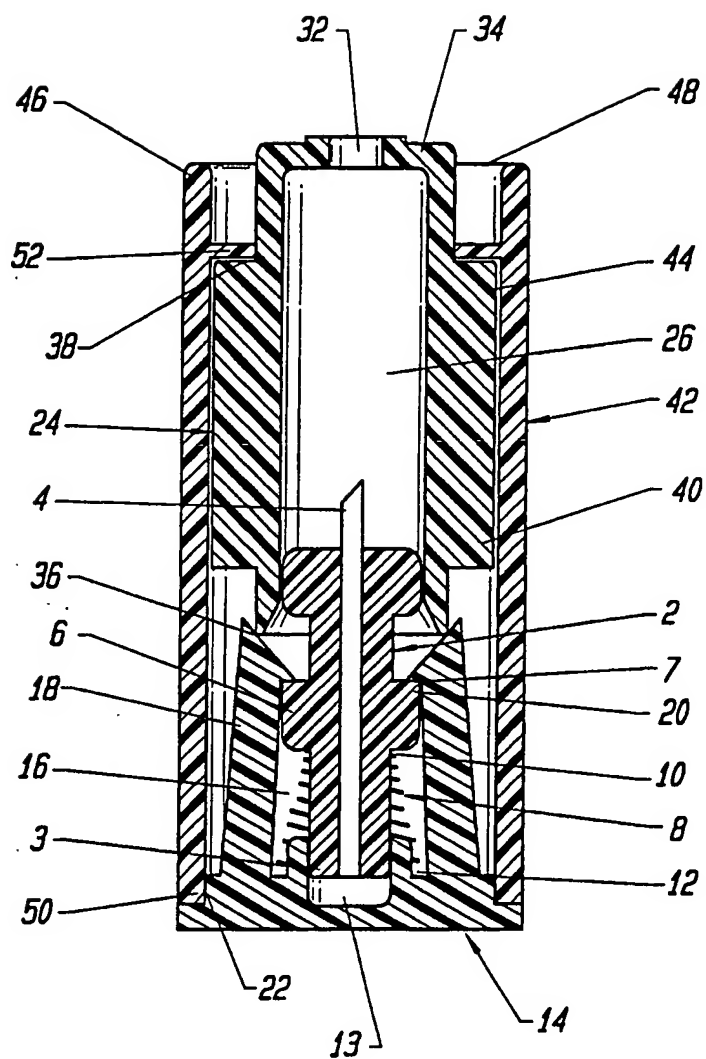


FIG. 1

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FIG. 6

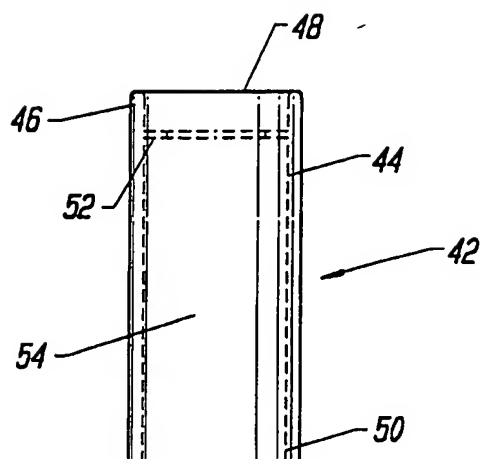


FIG. 5

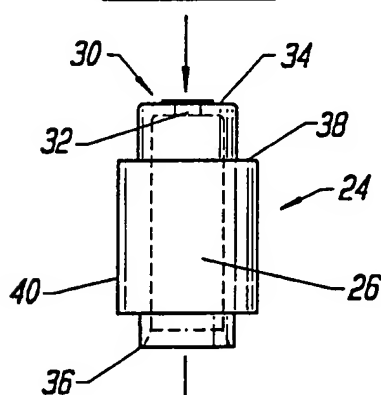


FIG. 2

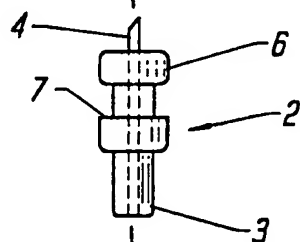


FIG. 3

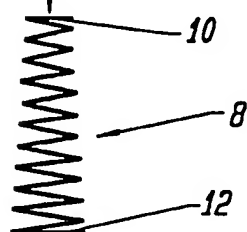
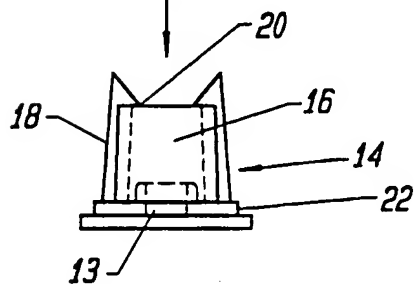


FIG. 4





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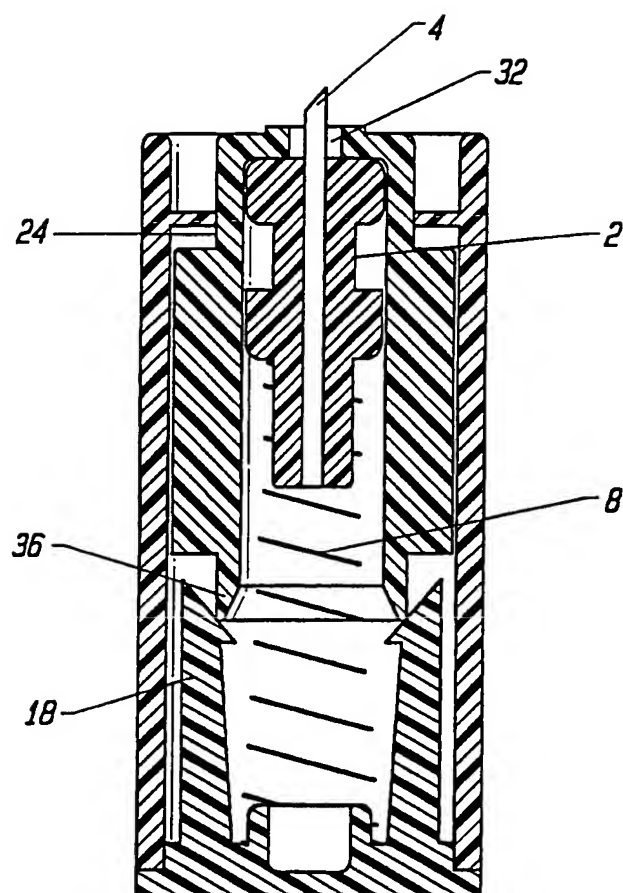


FIG. 7

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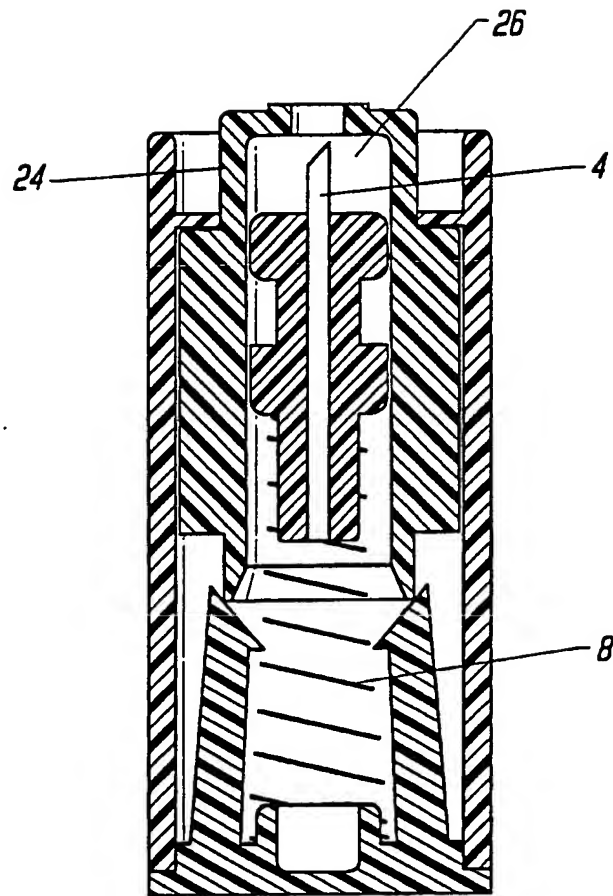


FIG. 8

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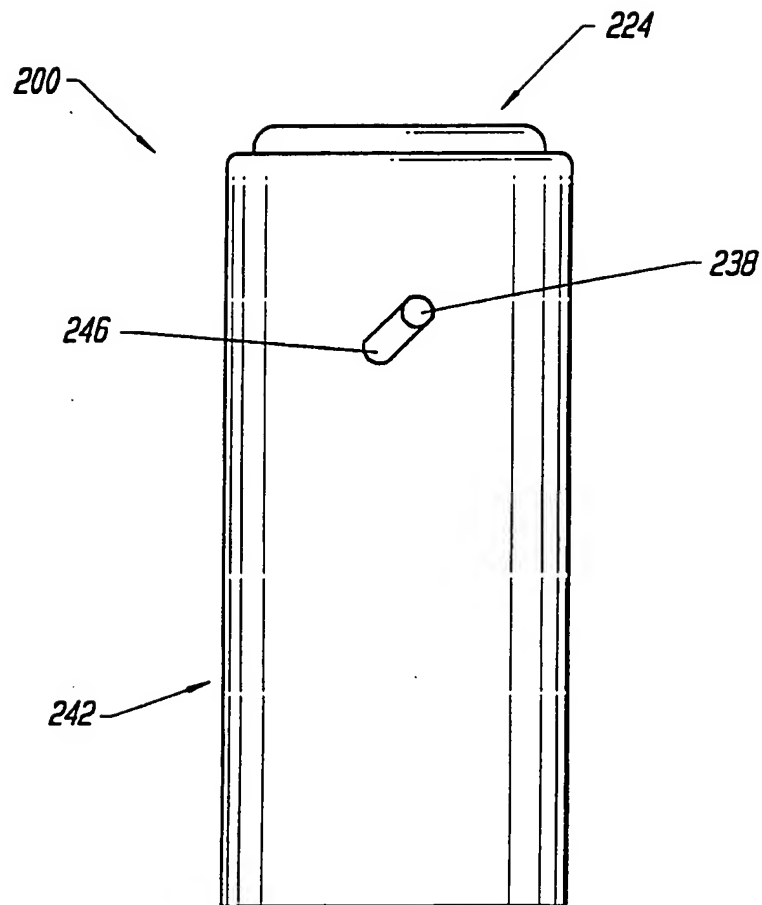


FIG. 9

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FIG. 13

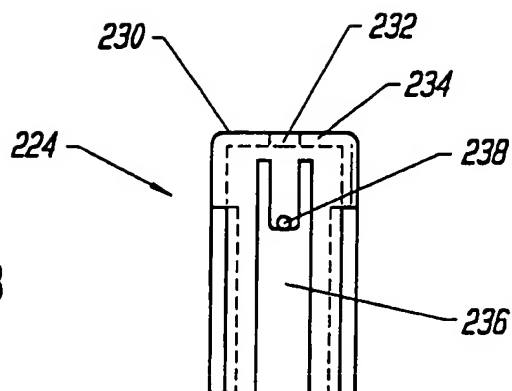


FIG. 10

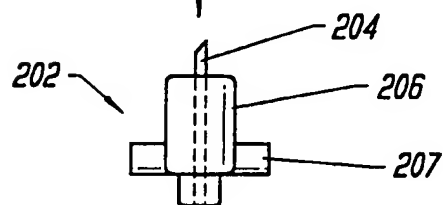
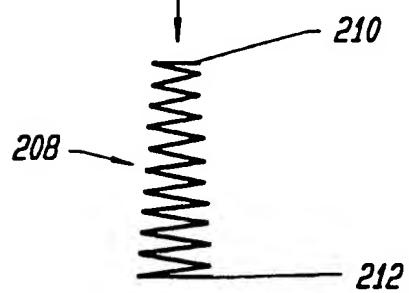


FIG. 11



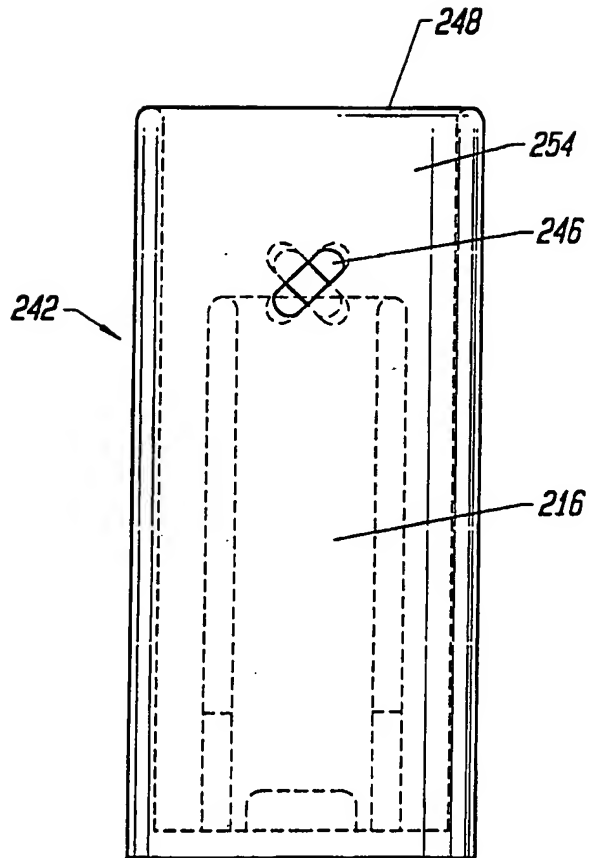


FIG. 12A

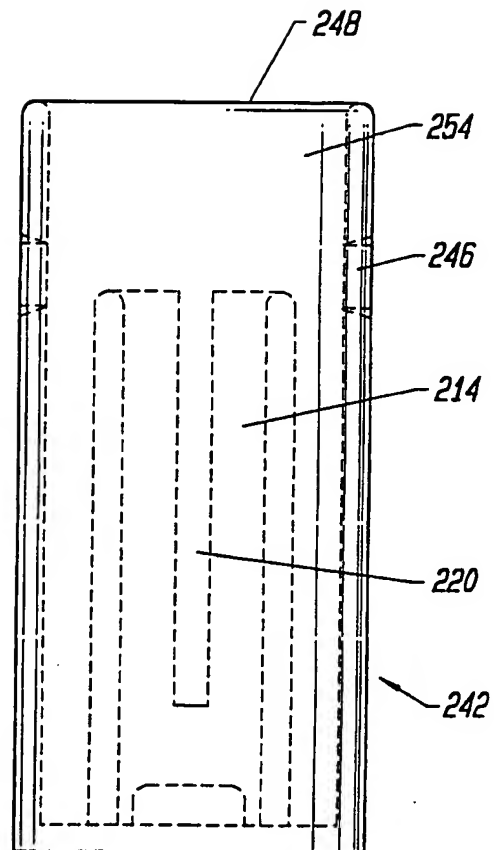


FIG. 12B

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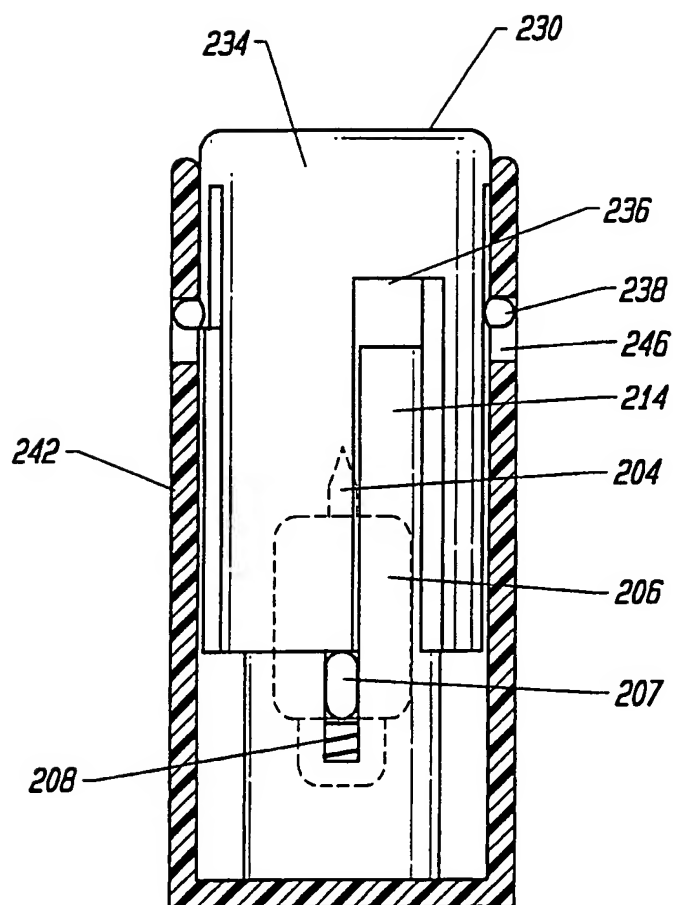


FIG. 14

SUBSTITUTE SHEET

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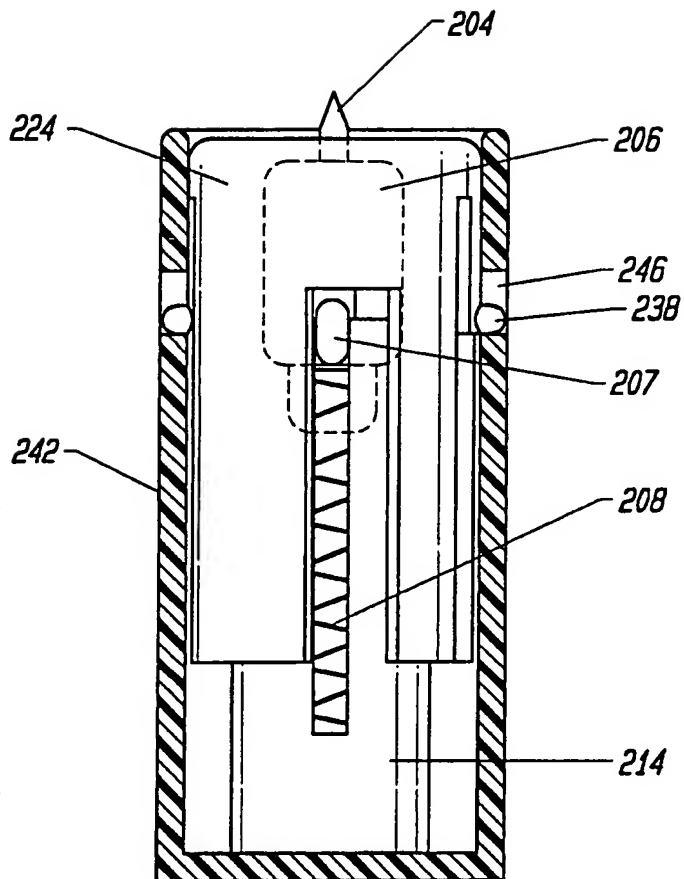


FIG. 15

SUBSTITUTE SHEET

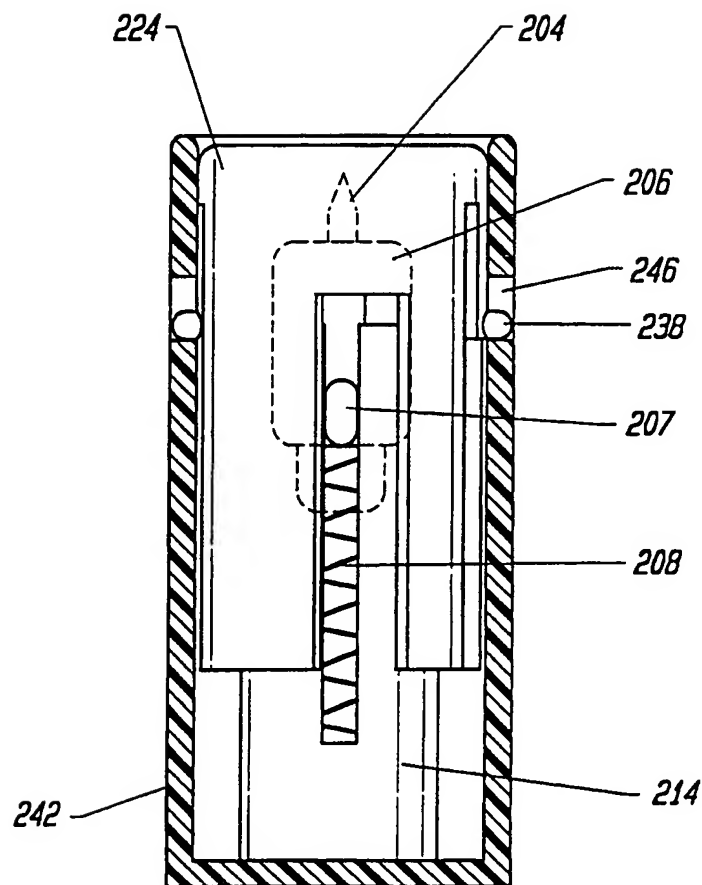


FIG. 16



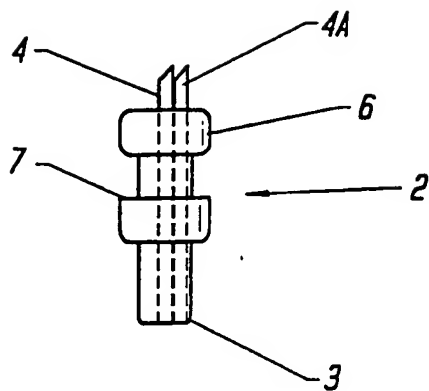


FIG. 17A

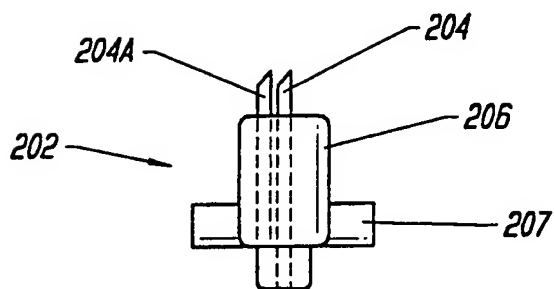


FIG. 17B

## INTERNATIONAL SEARCH REPORT

PCT/US92/09456

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :A61B 17/32

US CL :606/183,182

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/185,186; 604/137,157

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
<u>X</u> Y	US,A, 4,817,603 (TURNER ET AL) 04 APRIL 1989 See entire document	<u>1,17,19-28</u> 2-16,18
Y	US,A, 3,208,452 (STERN) 28 SEPTEMBER 1965 See entire document	11,18
Y	US,A, 4,653,513 (Dombrowski) 31 MARCH 1987 See entire document	2-16
Y	US,A, 5,026,388 (INGALZ) 25 JUNE 1991 See entire document	5,16

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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*L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*G*	document member of the same patent family
*O* document referring to an oral disclosure, use, exhibition or other means		
*P* document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 08 DECEMBER 1992	Date of mailing of the international search report 21 JAN 1993
Name and mailing address of the ISA/ Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. NOT APPLICABLE	Authorized officer <i>H. Leon Thaler</i> MICHAEL THALER Telephone No. (703) 308-2981